



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|-------------------|
| 10/567,109 | 11/30/2006 | Pavel Sebek | 285293US0PCT | 2898 |
| 22850 | 7590 | 04/13/2011 | EXAMINER | |
| OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P. 1940 DUKE STREET ALEXANDRIA, VA 22314 | | | | FISHER, ABIGAIL L |
| ART UNIT | | PAPER NUMBER | | |
| 1616 | | | | |
| NOTIFICATION DATE | | | DELIVERY MODE | |
| 04/13/2011 | | | ELECTRONIC | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

| | | |
|---|------------------------|---------------------|
| Advisory Action Before the Filing of an Appeal Brief | Application No. | Applicant(s) |
| | 10/567,109 | SEBEK ET AL. |
| | Examiner | Art Unit |
| | ABIGAIL FISHER | 1616 |

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 25 March 2011 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

a) The period for reply expires 5 months from the mailing date of the final rejection.

b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because

(a) They raise new issues that would require further consideration and/or search (see NOTE below);

(b) They raise the issue of new matter (see NOTE below);

(c) They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. Applicant's reply has overcome the following rejection(s): Rejection of claims 9-11 and 30-31 under 35 USC 112, first paragraph.

6. Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. For purposes of appeal, the proposed amendment(s): a) will not be entered, or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 2-12, 14-18 and 22-35.

Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.

12. Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____

13. Other: _____.

/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616

4/07/2011

Continuation of 3. NOTE: The amendments would require reconstruction of rejection and well as new rejections to address dependent claims 36 and 37.

Continuation of 11. does NOT place the application in condition for allowance because: Applicants arguments filed 3/25/11 are not persuasive. Mills et al. recognize that HMG-COA reductase inhibitors are unstable and Singh et al. expressly teaches that the amorphous form of atorvastatin is hydroscopic and unstable when exposed to oxygen. Therefore, the instability of the instantly claimed compound is known. Since the instability is already recognized, one of ordinary skill in the art would have been motivated to package the drug in packaging known to reduce exposure to air and moisture which include exposure to oxygen such as packaging in blister packages under an inert atmosphere. Since Singh et al. recognizes the drug is unstable to oxygen exposure and Watermen is directed to oxygen-sensitive drug packaging. Clearly, the two references are related art. While Waterman does not expressly teach atorvastatin, Waterman does teach other statins such as lovastatin and simvastatin. Therefore, the rejection is not one of hindsight but based on the teachings of the cited prior art. Since Waterman teaches the use of oxygen absorbers with structurally similar drugs (lovastatin and simvastatin vs. atorvastatin), one of ordinary skill in the art has a reasonable expectation of success. Applicants have not shown the unexpectedness of the oxygen absorbers with the specifically claimed statin. The examiner maintains that since the art already recognizes the instability of atorvastatin, it would have been obvious to one of ordinary skill in the art to package the drug under conditions to reduce exposure to moisture, air and oxygen to enhance stability. The art clearly recognizes that packaging under inert atmosphere and oxygen absorbers are methods of packaging which reduce exposure to moisture, air and oxygen. Therefore, the rejection is maintained since applicant has not provided any persuasive arguments to overcome the rejection.